भारतीय मानक

Indian Standard

IS 18307 : 2023

पृथक अंग स्नान

Isolated Organ Bath

ICS 07.140

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भारतीय मानक ब्यूरो
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Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Anatomy and Forensic Sciences Equipment Sectional Committee had been approved by Medical Equipment and Hospital Planning Division Council.

This standard describes the specifications for isolated organ bath which is used to study the drug action. It is used to study the interaction between a living organism and exogenous chemicals that alter normal biochemical function. Isolated organ bath experiment is one of the methods employed to quantify these interactions. Isolated tissue in its most basic form requires the use of a vessel or bath where the tissue resides ex-vivo. The life support is provided by the physiological solutions filled in the bath. A tissue holder is used to hang the tissue. A manipulator to dial in the correct tension on the prep, an isometric or isotonic transducer is used to measure the force. Optimum oxygen and heat are maintained in order to keep the tissue viable.

It is important that individuals following this procedure are experienced and aware of the experimental protocols, and be familiar with the human and animal safety, in order to avoid and damage during the experiment. It is not intended to be used to diagnose, treat or monitor a subject in hospital or domestic environment. Furthermore, it is not intended for the prevention, curing or alleviation of disease, injury or handicap. It should be installed, used and operated under the supervision of an appropriately qualified life-science researcher. The typical usage environment is a research or teaching lab or hospital. Environmental factors, temperature, humidity, ventilation, noise intensity and light intensity must be maintained at appropriate levels as they may contribute to the levels of mouse anxiety.

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards/Other Publications and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
IEC 61326-1 : 2020	Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

ISOLATED ORGAN BATH

1 SCOPE

This Indian Standard specifies requirements for isolated organ bath intended for research and teaching use. This standard covers the general description of standard materials, technical parameters, test settings, and procedures. The test methods described herein must follow the procedure strictly and are intended for use by individuals who have been trained, and are competent in performing the procedures.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on the standard are encouraged to investigate the possibility of applying the most recent editions of these standards:

IS No.	*Title*
IS 13450 (Part 1) : 2018/IEC 60601- 1 : 2012	Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (*second revision*)
IS/IEC 61010 : (Part 1) : 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 1 General requirements

3 REQUIREMENTS

3.1 Isolated Organ Bath

The system should comprise multiple transducers and accessories to acquire the drug’s effect on the tissue along with an analysis software. It is used for conducting two simultaneous isolated tissue studies. The software should offer comprehensive signal processing, data acquisition, data recording, display, and analysis features for a variety of teaching and research application. The isolated organ bath should have electro-valve based two chamber organ baths to carry out simultaneous two isolated tissue experiments. The system should be compact and all in one structure with no external glassware.

3.2 Self-Test

The isolated organ bath should be able to perform a diagnostic self-test each time it is switched on. Before connecting it to the computer for the first time, it should test that the system is functioning properly.

3.3 Hardware and Software

3.3.1 The system should have a software-controlled USB based minimum two channels and up to eight channels data acquisition system with + 2 mV to + 10 V in 12 steps amplification range and variable and high sampling rate up to 400 kHz (aggregate speed), 16-bit ADC resolution on all gain ranges.

3.3.2 It should have programmable gain, variable sampling speed on each channel.

3.3.3 The structure of isolate organ bath should be built of thick perspex/glass and must include immersed tissue chambers, pre-heating reservoir coils, gas diffusers, tissue holders, micro positioners, a water pump, and thermostat controller to maintain temperature.

3.3.4 Force transducers should be provided to measure forces under isometric conditions in single range of 0 mg to 25 g.

3.3.5 Tissue hooks or tissue clips should be provided for different Tissues.

3.3.6 The hardware should have adjustable gas diffuser for oxygenation and electro valves should allow simultaneous or individual emptying and refilling of tissue chambers at the press of a button.

3.3.7 The different sizes of tissue chambers that is, 5 ml, 10 ml, 25 ml or 50 ml should be provided with an easy replacement option. The electro-valves must have a provision to be operated manually or by using the digital output of the data acquisition system.

3.3.8 The hardware should include a 2 channel (0 mA to 100 mA) stimulator. It should provide a mono/bipolar output and several stimulation modes such as single, continuous and frequency regulated steps.

3.3.9 All protocol parameters can be entered from the front panel and can be stored in internal program memories and can be easily reloaded.

3.3.10 The device shall have facility to connect to a computer using the standard RS 232 serial interface.

3.3.11 The Software should be able to control the compact multi-channel amplifier with manual or automatic zeroing circuitry. It should be able to perform online and offline analysis of force waveforms with calculation of slopes, indices and time intervals. Software should allow recording, analysing, storing, and printing the data. The analysis module should tabulate the results automatically or manually, generate instantaneous Hill curves, displays single or multiple response curves, calculates EC_{50} and hill slopes, exports the results in XML and tab-delimited text format for use in other applications. The software should have free update and upgrade for 5 yrs.

3.3.12 The system should be supplied with Intel i5 processor-based desktop computers with DVD RW, minimum 4GB RAM and 500 GB hard disk and 21 inch LED monitor with stand and other required accessories and 1kVA UPS.

3.4 Safety Requirements

The device should comply with all safety requirements as described in IS 17724 (Part 1)/ IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 1 General requirements.

3.5 Troubleshooting

The troubleshooting steps should be instructed in the user manual of the system.

3.6 Cleaning and Maintenance

The cleaning guidelines of organ bath should be instructed in the user manual. The system should be maintenance-free and should not require periodic calibration or adjustment to ensure safe operation. Internal diagnostic software should able to perform system checks during power up and will report errors if a significant problem is found.

4 GENERAL TEST CONDITIONS

4.1 Subject

Subjects (rodent) before testing should be acclimated to testing environment and experimenter.

4.2 Environmental Factors

Environmental factors may contribute to the levels of anxiety within the subject therefore temperature, humidity, ventilation, noise intensity and lighting intensity must be maintained at levels appropriate. In order to avoid anomalous results, it is essential that the subject be kept in a uniform environment before and after testing

4.3 Temperature

The temperature range in the testing room may be adjusted at 5 °C to 35 °C for subject. The temperature range could change depending on the experimental protocol.

4.4 Humidity

The humidity range in the testing room may be adjusted at 50 percent ± 20 percent.

4.5 Lighting

Room lighting in the testing room should be appropriate.

4.6 Noise

The ambient background noise levels in the procedure room may be adjusted to 60 dB to 70 dB. Audible timers should be avoided during this test.

5 TEST METHODS

5.1 Procedure

Students/Researchers are advised to wear a white laboratory coat, glasses, and gloves throughout the practical, to avoid potential contamination with bacteria from intestinal contents or blood borne pathogens. Animal subject should be anesthetized before the experiment. A segment of animal tissue is dissected for the study/research purpose. The length of tissue should be transferred from the animal to the organ bath as quickly as possible to avoid deterioration of the tissue. A force transducer is connected to a data acquisition system and to the tissue inside the tissue chamber filled with physiological saline solution. The tissue should be connected to the force transducer using tissue hook and thread. The thread should not taut enough to register contractions with the tension transducer but not so tight as to damage the contractile machinery of the tissue. The tissue's temperature is maintained using thermostat controller and oxygen is provide to the tissue either through oxygen cylinder or aerator. After connecting the transducers, the experiment should start for collecting the baseline for first 5 minutes to 10 minutes. The experimenter can start and record the study of drug's effect on the tied tissue.

6 PARAMETERS

The isolated organ bath system should be able to acquire and analyse the below mentioned parameters:

a) Forces under isometric condition;
b) Instantaneous Hill curves;
c) Single or multiple response curves;
d) Study reaction time, pulse transit time and peak waveform analysis; and
e) EC 50 (Estimated concentration of drug that generates 50 percent of the muscle's maximum response) and Hill slopes.

7 REGULATORY SYMBOLS

The device shall comply to IS 13450 (Part 1) : 2018/IEC 60601- 1 : 2012 and IS 17784 (Part 1)/IEC 61326-1, and carry one or more of the safety symbols below.

7.1 B (Body Protected) Symbol

Equipment marked with this symbol is suitable for connection to humans and animals provided there is not direct electrical connection to the heart and provides basic protection against electric shock.

7.2 BF (Body Protected-Floating) Symbol

This means that the input connectors are suitable for connection to humans and animals provided there is no direct electrical connection to the heart and provides increased protection against electric shock over B rated applied parts.

7.3 Warning Symbol

The exclamation mark inside a triangle means that the supplied documentation must be consulted for operating, cautionary or safety information before using the device.

7.4 WEEE Directive Symbol

Unwanted equipment bearing the Waste Electrical and Electronic Equipment (WEEE) directive symbol requires separate waste collection.

7.5 Date of Manufacture/Manufacturer's Name Symbol

This symbol indicates the date of manufacture of the device and the name of the manufacturer

8 DATA RECORDS AND REPORTS

The software should be able to record and save the recorded data for desired interpretation of the data.

9 OPERATING MANUAL

Each isolated organ bath system shall be accompanied by an operating manual which shall contain the following information:

a) Instructions and plan for installation,
b) Operation of the apparatus, and
c) Routine maintenance and service.

10 MARKING AND PACKING

10.1 The apparatus shall be legibly and indelibly marked at a suitable place with the designation number; the manufacturer's name, initials or recognized trade-mark; serial number; and the country of manufacture.

10.2 The apparatus may be packed as agreed to between the purchaser and the supplier.

10.3 The apparatus shall be securely packed, in any manner, acceptable to the purchaser, so as to minimize the risk of damage in handling, transport and storage.

10.4 BIS Certification Marking

10.4.1 The isolated organ bath may also be marked with the Standard Mark.

10.4.2 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Foreword*)

COMMITTEE COMPOSITION

Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

Organization	*Representative(s)*
Maulana Azad Medical College, New Delhi	DR SABITA MISHRA **(*Chairperson*)**
Association of Indian Medical Device Industry, New Delhi	SHRI RAJESH KHATRI MRS LALITA KHATRI (*Alternate*)
CSIR-Indian Institute of Chemical Technology, Hyderabad	DR A. KIRAN KUMAR
Sri Ramachandra Medical College & Research Institute, Chennai	DR KALPANA RAMACHANDRAN DR SENTHIL KUMAR (*Alternate*)
Directorate General of Health Services, Delhi	DR ANITA TULI DR M. K. WAHI (*Alternate*)
Federation of Indian Chambers of Commerce and Industry (FICCI), New Delhi	SHRI VIJAY KUMAR DR SANDEEP SEWLIKAR (*Alternate*)
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Indian Medical Association, Delhi	DR R. V. ASOKAN DR N. V. KAMAT (*Alternate*)
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VMMC & Safdarjung Hospital, New Delhi	DR MANOJ KUMAR WAHI DR G. A. SUNIL KUMAR SHARMA (*Alternate*)
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Member Secretary
MS NAGAVARSHINI M.
SCIENTIST 'B'/ASSISTANT DIRECTOR
(MEDICAL EQUIPMENT AND HOSPITAL PLANNING), BIS

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